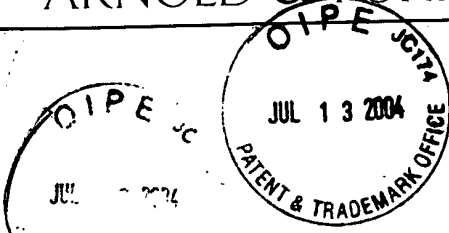


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July 13, 2004

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Art Unit: 1631  
Examiner: J. Martinell  
Conf. No.: 8906

Re: U.S. Patent Application Serial No. 10/021,323 filed December 12, 2001  
Inventors: Jill DEIKMAN *et al.*  
Title: Nucleic Acid Molecules and Other Molecules Associated with Plants  
Atty Dkt.: 16517.295

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appellants' Brief (in triplicate), with attached Appendix A; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Authorization is hereby given to charge the statutory fee of \$330.00 for filing Appellants' Brief to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.295. A duplicate copy of this letter is enclosed.

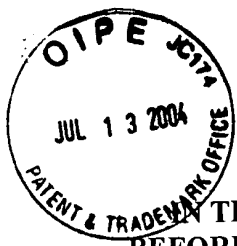
In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Appellants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.295. A duplicate copy of this letter is enclosed.

Sincerely,

David R. Marsh  
by: Holly L. Prutz (Reg. No. 47,755)

David R. Marsh (Reg. No. 41,408)  
Holly L. Prutz (Reg. No. 47,755)

Enclosures



THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

Jill DEIKMAN *et al.*

Appln. No.: 10/021,323

Filed: December 12, 2001

Confirmation No. 8906

Art Unit: 1631

Examiner: J. MARTINELL

Atty. Docket: 16517.295

For: Nucleic Acid Molecules and Other Molecules Associated with Plants

## APPELLANTS' BRIEF

### Mail Stop Appeal Brief – Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on May 13, 2004. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

### 1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

### 2. Related Appeals and Interferences

Appellants are unaware of any Appeals or Interferences related to this Appeal.

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### **3. Status of Claims**

Claims 1, 2 and 4-17 are pending. Non-elected claim 3 was cancelled in Appellants' Response to Office Action mailed August 26, 2003, without prejudice to or disclaimer of the underlying subject matter. Claims 1, 2, and 4-17 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Appellants appeal all of the rejections of claims 1, 2 and 4-17.

### **4. Status of Amendments**

Appellants have not filed any amendments in this case subsequent to the Final Office Action mailed February 13, 2004("Final Action").

### **5. Summary of Invention**

The invention is directed to an isolated nucleic acid molecule that encodes a plant protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 13. Specification at page 7, lines 5-7. The invention is also directed to a transformed plant having a nucleic acid molecule which comprises: (a) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule; (b) a structural nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 13 or complements thereof; and (c) a 3' non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule. Specification at page 7, lines 22-30. The invention is also directed to a substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 90% identity with a nucleic acid sequence of SEQ ID NO: 13 or a complement thereof. Specification at page 15, lines 4-21. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 13 or a complement thereof.

*Id.*

## 6. Issues

The issues in this Appeal are:

(a) whether claims 1, 2 and 4-17 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1, 2 and 4-17 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claims 4 and 5 are unpatentable under 35 U.S.C. § 112, second paragraph for alleged indefiniteness..

## 7. Grouping of Claims

Claims 1, 2 and 4-17 remain in this case. Claims 1, 4, 11, and 16 are independent. All of the claims at issue do not stand or fall together. The separate patentability of claims 1-2, 4-10, 11-15 and 16-17 is addressed in Sections 8.B(4) below. A copy of the pending claims on appeal is attached hereto as Appendix A.

## 8. Argument

### A. Summary of Appellants' Position

As the Supreme Court said in *Brenner v. Manson*, the “basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form.” 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Appellants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism. This benefit is specific, not vague or unknown, and it is a “real world” or substantial benefit. Because the claimed nucleic acid molecules provide at least these benefits, they satisfy the utility

requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Appellants have distinctly claimed the invention. It is well-settled that claims are to be read through the eyes of one having ordinary skill in the art and in light of the specification. *United States v. Telectronics, Inc.*, 857 F.2d 778, 786, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). Because the claims read in light of the specification by one of ordinary skill in the art distinctly claim the invention, the requirements of 35 U.S.C. § 112, second paragraph are satisfied.

#### **B. The Claimed Nucleic Acids Have Legal Utility**

Claims 1, 2 and 4-17 stand rejected under 35 U.S.C. § 101 as allegedly not supported by a “specific, substantial, and credible utility for either SEQ ID NO: [13] or a polypeptide encoded by SEQ ID NO: 13 nor is a specific, substantial, and credible utility readily apparent to one of skill in the art from the disclosure and what is known in the art.” Office Action mailed August 26, 2003, at page 3. However, the Examiner asserts that none of these utilities are specific. Final Action at page 2. The Examiner goes on to assert that “[t]he long, long list of utilities listed beginning on page 30 is no disclosure of a specific, substantial, and credible utility for SEQ ID NO: 13 because a list of hopes and possibilities does not tell those of skill in the art what the invention is actually useful for.” *Id.*

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of “practical utility” developed by the courts after *Brenner v. Manson*. The “threshold for utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v.*

*Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. See *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) (“when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown”).

The courts have expressed a test for utility that hinges on whether an invention provides an “identifiable benefit.” *Juicy Whip*, 185 F.3d at 1366, 51 U.S.P.Q.2d at 1702. For analytical purposes, the requirement for an “identifiable benefit” may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or “substantial” benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be “totally incapable of achieving a useful result,” *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Appellants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use as genetic markers, use to identify the presence or absence of a polymorphism, and use as a hybridization probe for monitoring expression. See, *e.g.*, specification at page 23, line 10, through page 25, line 16, page 35, line 21 through page 40, line 24 and page 44, line 8, through page 49, line 21. Any of these utilities described alone is enough to satisfy Section 101. Because Appellants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

**(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*,  
They Have Specific Utility**

The Examiner acknowledges that the specification describes many utilities for the present invention. Final Action, at page 2. As mentioned, the specification discloses multiple utilities for the claimed nucleic acid molecules,<sup>1</sup> including use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,<sup>2</sup> and use as molecular markers.<sup>3</sup> The Examiner argues, however, that such uses are not specific. *Id.*

**(a) Identifying the Presence or Absence of a Polymorphism**

More particularly, one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 35 line 21 through page 40, line 24. The Examiner appears to argue that this utility, like use for genetic mapping and many of the asserted utilities, is “not specific since any genomic DNA may be used for such a purpose.” Final Office Action at page 2. However, the Examiner does not provide any support (legal or factual) for the proposition that the asserted uses, for example detection of polymorphisms using the claimed nucleic acid molecules, are not legal utilities.

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<sup>1</sup> It is irrelevant whether the corresponding polypeptide has utility because Appellant is not relying solely on utility of the polypeptide to establish utility of the claimed nucleic acid molecules.

<sup>2</sup> It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, seed germination, development or both.

<sup>3</sup> One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of *e.g.*, agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such “tools” have legal utility. “Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds).” MPEP § 2107 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.<sup>4</sup> Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids,

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<sup>4</sup> For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled “Chlorine Specific Gas Chromatographic Detector.”



not from the use of other molecules. Such use provides an immediate benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

**(b) Probes for Other Molecules or Source for Primers**

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because “the instant application gives no information as to the specific location of SEQ ID NO: 13, so the utility is not really disclosed....” Final Action, at page 2. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*, barley, *Brassica*..., sunflower, oil palm, and *Phaseolus*, etc.<sup>5</sup> Specification at page 18, lines 21 through 26. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. See *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). Accord *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Appellants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk or alternatively in chromosome landing. Specification at page 33, line 31, through page 35, line 2. The Examiner denigrates that utility by asserting that it is not specific because it is generally applicable to any nucleic

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<sup>5</sup> Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Appellant to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

acid. Final Action at page 2. This is not correct. The claimed nucleic acid molecules are particularly useful, for example, to identify markers and isolate promoters in cotton plants. *See, e.g.*, specification at page 30, lines 1-22, page 69, lines 12-18, and the Sequence Listing.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *e.g.*, chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not “specific” to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate genes in cotton plants. *See, e.g.*, specification at page 30, lines 2-22. A random nucleic acid molecule does not provide an equally good starting point to isolate such genes. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be “less effective than existing devices but nevertheless meet the statutory criteria for patentability.” *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

**(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility**

The Final Action also appears to assert that the disclosed uses are legally insufficient because they are not “substantial” utilities. Final Action at page 2. The touchstone of “substantial” utility is “real world” or “practical utility.” *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). “ ‘Practical utility’ is a shorthand way of attributing ‘real world’ value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.” *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) (“tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use”).<sup>6</sup>

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant’s genetic profile, like the information about a

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<sup>6</sup> *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

**(3) The Disclosed Utilities Are Credible to One of Skill in the Art**

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.<sup>7</sup> A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); see *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107 at 2100-41.

Appellants have explicitly identified specific and substantial utilities. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities.

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<sup>7</sup> Examples of incredible utilities are given in MPEP § 2107 at page 2100-34, and include:

an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

**(4) Claims 4-10 are separately patentable**

The Examiner argues that the claimed nucleic acid molecules lack utility apparently because “[t]he use of DNA for genetic mapping is not a specific use since any genomic DNA may be used for such a purpose.” Final Action at page 2. The Examiner additionally argues that “the instant application gives no information as to the specific genetic location of SEQ ID NO: 13.....” Such a basis for rejection, even if valid, would not apply to claims 4-10, which are directed to “[a] transformed plant.” The Examiner provides no evidence that the genetic location is necessary for the other utilities described in the specification, for example, as probes, to detect the presence or absence of polymorphisms, all of which have been asserted in the specification.

**C. The Claimed Nucleic Acids Are Enabled by the Specification**

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1, 2, and 4-17 were rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 3. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that “the enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), quoting *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. See *In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed.

Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) (“pure conjecture” does not substantiate rejection for lack of enablement).

**D. The Claims Particularly Point Out and Distinctly Claim the Subject Matter Which Appellants Regard as Their Invention**

Claims 4 and 5 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Final Action at page 2. More specifically, the Examiner indicates that the recitation of “structural nucleic acid” is vague and indefinite. *Id.* According to the Examiner, “[t]he application confuses the term ‘structural nucleic acid’ with the term of art, ‘structural gene’....” *Id.* The Examiner’s position is unfounded.

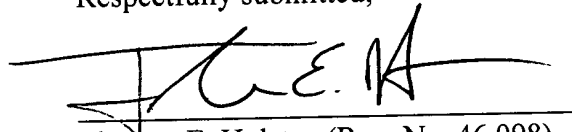
The claims are to be read in light of the specification. *See In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 169 (1991). Furthermore, it is axiomatic that claims are always construed in light of the specification, of which they are a part. *Netword L.L.C. v. Centraal Corp.*, 242 F.3d 1347, 1352, 58 U.S.P.Q. 2d 1076, 1079 (Fed. Cir. 2001); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1118, 1 U.S.P.Q. 2d 1563, 1566 (Fed. Cir. 1987). The specification describes, for example, the use structural nucleic acid molecules in the transformation of plants. *See, e.g.*, Specification at page 13, lines 11-16. Furthermore, original claim 4 recites “a transformed plant having a nucleic acid molecule which comprises: (a) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule; (b) a structural nucleic acid molecule comprising a nucleic acid sequence of [...SEQ ID NO: 13...]; and (c) a 3’ non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides

to a 3' end of said mRNA molecule.”<sup>8</sup> A person skilled in the art, reading the specification and the claims as a whole, would readily understand the phrase “structural nucleic acid.”<sup>9</sup> As such, the phrase “structural nucleic acid” satisfies the requirements of 35 U.S.C. 112, second paragraph and the rejection should be reversed.

### CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



Thomas E. Holsten (Reg. No. 46,098)  
Holly Logue Prutz (Reg. No. 47,755)  
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Date: July 13, 2004

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Monsanto Company

<sup>8</sup> Original claim 4 as presented recites:

A transformed plant having a nucleic acid molecule which comprises:

- (a) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule;
- (b) a structural nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 17880 or complements thereof;
- (c) a 3' non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

<sup>9</sup> Appellant further notes that “[t]he mere fact that a term or phrase used in the claims has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure.” MPEP § 2173.05(e).

## APPENDIX A

1. An isolated nucleic acid molecule that encodes a plant protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 13.
2. The isolated nucleic acid molecule according to claim 1, wherein said plant protein is a cotton protein.
4. A transformed plant having a nucleic acid molecule which comprises:
  - (a) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule;
  - (b) a structural nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 13 or complements thereof; and
  - (c) a 3' non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.
5. The transformed plant according to claim 4, wherein said structural nucleic acid molecule is a complement of SEQ ID NO: 13.
6. The transformed plant according to claim 4, wherein said plant is soybean, wheat, cotton or maize.
7. The transformed plant according to claim 4, wherein said plant is maize.
8. The transformed plant according to claim 4, wherein said plant is soybean.



9. The transformed plant according to claim 4, wherein said plant is wheat.
10. The transformed plant according to claim 4, wherein said plant is cotton.
11. A substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 90% identity with a nucleic acid sequence of SEQ ID NO: 13 or a complement thereof.
12. The substantially purified nucleic acid molecule according to claim 11, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 95% identity with a nucleic acid sequence of SEQ ID NO: 13 or a complement thereof.
13. The substantially purified nucleic acid molecule according to claim 11, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% identity with a nucleic acid sequence of SEQ ID NO: 13 or a complement thereof.
14. The substantially purified nucleic acid molecule according to claim 11, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 99% identity with a nucleic acid sequence of SEQ ID NO: 13 or a complement thereof.
15. The substantially purified nucleic acid molecule according to claim 11, wherein said nucleic acid molecule further comprises a region having a single nucleotide polymorphism.
16. A substantially purified nucleic acid molecule, wherein said nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 13 or a complement thereof.

17. The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 13 or a complement thereof.